

Remarks

Claims 1-3, 5, 8, 11, 13, 15, 19-24, 31, 32, 34, and 79 were pending in the subject application and are now before the Examiner for further consideration. Favorable consideration of the pending claims is respectfully requested.

Claims 1-3, 5, 8, 11, 13, 15, 24, 31, and 79 have been rejected under 35 U.S.C. §102(a) as being anticipated by Olszta R9 (“Biomimetic mineralization of type-I collagen” presented at 7<sup>th</sup> Int. Conf.-The Chemistry and Biology of Mineralized Tissues, November 4-9, 2001, Sawgrass, FL) or Olszta R11 (“Biomimetic mineralization of type-I collagen” presented at UEF Biomimetic Engineering Conference, March 3-7, 2002, Destin, FL) or Olszta R27 (“Biomimetic Mineralization of Collagen for Nanostructured Composites” poster materials, June 2001, Department of Materials Science and Engineering, University of Florida, Gordon Research Conference). The applicants respectfully traverse.

The applicants respectfully maintain that the Olszta R27 reference does not qualify as a publication under 35 U.S.C. §§ 102 and 103 since it is material presented at a Gordon Research Conference. As noted in Exhibit A submitted with the Amendment of October 30, 2007, as well as in the remarks of that Amendment, the Olszta R27 reference was not disclosed to conference attendees without restriction. Specifically, information printed from the Gordon Research Conferences Home Page stated, in the “format” section at page 2,

To encourage open communication, each member of a Conference agrees that any information presented at a Gordon Research Conference, whether in a formal talk, poster session, or discussion, is a private communication from the individual making the contribution and is presented with the restriction that such information is not for public use. The recording of lectures by any means, the photography of slide or poster material, and printed reference to Gordon Research Conferences papers and discussion is prohibited. Scientific publications are not to be prepared as emanating from the Conferences. Authors are requested to omit references to the Conferences in any publication. Guests are not permitted to attend the Conference lectures and discussion sessions. Each member of a Conference acknowledges and agrees to these restrictions when registration is accepted and as a condition of being permitted to attend a Conference...

The applicants respectfully draw the Examiner's attention to *In re George* (BPAI, Appeal No. 86-0278, 01/29/87), in which the Board held that a research report released only to members of the research institute was not a printed publication. In *George*, the research institute had a policy of confidentiality that was not even stated in writing; however, since the institute "practiced a policy of confidentiality," the Board determined that the report did not qualify as a printed publication. In the case of the Olszta R27 presentation at the Gordon Conference, not only was there a confidentiality policy of which each participant was aware, the policy was, in fact, reduced to writing. Thus, the Olszta R27 reference was subject to an even stronger confidentiality policy than the report in *George*, and it is not available as prior art.

Additionally, the MPEP states in §2132 with regard to references qualifying as prior art under 35 U.S.C. §102(a), "[t]he statutory language 'known or used by others in this country' (35 U.S.C. § 102(a)), means knowledge or use which is accessible to the public." *Carella v. Starlight Archery*, 804 F.2d 135, 231 USPQ 644 (Fed. Cir. 1986). Additionally, "[t]he knowledge or use is accessible to the public if there has been no deliberate attempt to keep it secret." *W. L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983); emphasis added. Moreover, §2128.01(II) of the MPEP declares that, "[a] paper which is orally presented in a forum open to all interested persons constitutes a 'printed publication' if written copies are disseminated without restriction." *Massachusetts Institute of Technology v. AB Fortia*, 774 F.2d 1104, 1109, 227 USPQ 428, 432 (Fed. Cir. 1985); emphasis added.

In this case, the oral presentation of the R27 reference given at the Gordon Conference was not without restriction. It is clear that the information contained in the presentation was not accessible to the public, as required to be prior art under 35 U.S.C. §102(a). Thus, the applicants respectfully submit that the Olszta R27 reference is not available as prior art.

Furthermore, the applicants respectfully maintain that the Olszta R9, Olszta R11, and Olszta R27 references are disqualified as prior art under 35 U.S.C. §§ 102 and 103 because the subject matter disclosed in the references and relied on in the rejections was not the work of "another," as required for a rejection under §102 or §103, but rather originated with the applicants of the subject application.

While the applicants recognize the Examiner's assertion that the present case is not identical to the situation of *In Re Katz*, the applicants respectfully submit that the Olszta R9, Olszta R11, and Olszta R27 references are nonetheless the work of the applicants of the present application. The MPEP states that, "[w]here the applicant is one of the co-authors of a publication cited against his or her application, ... the applicant may overcome the rejection by filing a specific affidavit or declaration under 37 C.F.R. §1.132 establishing that the article is describing applicant's own work." *In re Katz*, 687 F.2d 450; 215 USPQ 14 (CCPA 1982); MPEP 715.01(c); 706.02(b).

The Gower Declaration under 37 C.F.R. §1.132, filed December 20, 2006 states that the subject matter disclosed in the cited references, and relied on by the Examiner, was the invention of the inventors on the subject application. The Office Action of February 5, 2008 indicates that the Declaration is not persuasive because it "fails to establish that Dr. Douglas was also involved in conceiving the specific procedures described in the Olszta" references. While the applicants do not necessarily agree with this assertion, the relevant consideration should actually be whether the Gower Declaration establishes that Dr. Douglas was involved in the conception of the process of the claimed invention, as described in the Olszta R9, Olszta R11, and Olszta R27 references.

In paragraph 4 of the Gower Declaration, Dr. Gower states that "Dr. Douglas, Dr. Olszta, and I contributed to the conception of mineralizing a collagen matrix using the process of the invention" (emphasis added). An uncontradicted, unequivocal statement from the applicants regarding the subject matter disclosed in an article, patent, or published application will be accepted as establishing inventorship. *In re DeBaun*, 687 F.2d 459, 463; 214 USPQ 933, 936 (CCPA 1982); *Ex parte Kroger*, 218 USPQ 370 (Bd. App. 1982); MPEP 716.10.

Even assuming, for the sake of argument, that the Gower Declaration fails to establish that Dr. Douglas was involved in conceiving the specific procedures described in the Olszta R9, Olszta R11, and Olszta R27 references, the Declaration clearly shows that Dr. Douglas contributed to the subject matter of the references disclosing the claimed invention. The Declaration need not prove that Dr. Douglas was involved in the conception of all subject matter in the references, including each specific procedure described.

As discussed in the Gower Declaration, the only reason Dr. Douglas was not listed as a co-author on the Olszta references is because he did not participate in the presentations and was not directly involved in carrying out the experiments described in the presentations. The applicants respectfully note that inventors are the person or persons who are the first to conceive the invention; reduction to practice is not required to establish inventorship. Conception can be defined as “the formation, in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice”. *Hybritech Incorporated v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 87 (Fed Cir. 1986) quoting 1 Robinson on Patents 532 (1890); *Coleman v. Dines*, 224 USPQ 857, 862 (Fed. Cir. 1985). As indicated in the applicants’ previous response, authorship of a publication does not give rise to any presumption with respect to inventorship.

Therefore, the Olszta R9, Olszta R11, and Olszta R27 references are not available as prior art against the present application.

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §102(a) is respectfully requested.

Claims 19-21 and 23 have been rejected under 35 U.S.C. §103(a) as being obvious over Olszta R9, R11, or R27 in view of Liu (U.S. Patent No. 6,300,315 B1). Claim 22 has been rejected under 35 U.S.C. §103(a) as being obvious over Olszta R9, R11, or R27 in view of Liu (U.S. Patent No. 6,300,315 B1) and further in view of Rhee *et al.* (U.S. Patent No. 5,800,541). Claim 32 has been rejected under 35 U.S.C. §103(a) as being obvious over Olszta R9, R11, or R27 in view of Connelly *et al.* (U.S. Patent No. 6,995,013 B2). Claim 34 has been rejected under 35 U.S.C. §103(a) as being obvious over Olszta R9, R11, or R27 in view of Song *et al.* (U.S. Patent No. 5,418,222). The applicants respectfully traverse.

Each of the rejections under 35 U.S.C. §103(a) is based on the Olszta R9, R11, and R27 presentations as primary references. The applicants’ remarks presented above with respect to the rejection under §102(a) are hereby incorporated in their entirety. The other cited references do not teach or suggest the applicants’ claimed invention. Liu, Rhee *et al.*, Connelly *et al.*, and Song *et al.* fail to disclose or suggest the biomimetic organic/inorganic composite recited in the currently pending claims.

Furthermore, the applicants respectfully point out that the earliest priority date for Connelly *et al.* is July 8, 2002. The present application claims priority to application 60/373,801, filed April 18, 2002, throughout which written support for the currently pending claims can be found. Thus, the priority date of the subject application is nearly three months earlier than the priority date of Connelly *et al.*, and the Connelly patent is therefore not prior art.

Accordingly, reconsideration and withdrawal of each rejection under 35 U.S.C. §103(a) is respectfully requested.

In view of the foregoing remarks and amendments to the claims, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

The applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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